

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIFOR FRESENIUS MEDICAL CARE)
RENAL PHARMA LTD. and VIFOR)
FRESENIUS MEDICAL CARE RENAL)
PHARMA FRANCE S.A.S.,)

Plaintiffs,)

v.)

LUPIN ATLANTIS HOLDINGS SA,)
LUPIN PHARMACEUTICALS, INC., and)
TEVA PHARMACEUTICALS USA, INC.,)

Defendants.)

C.A. No. 18-390-MN

REDACTED PUBLIC VERSION

**DEFENDANTS' LETTER TO
THE HONORABLE MARYELLEN NOREIKA
IN OPPOSITION TO PLAINTIFFS' MOTION TO STRIKE**

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS, MCLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com

OF COUNSEL:

William A. Rakoczy
Anuj K. Wadhwa
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, Illinois 606054
(312) 222-6301
wrakoczy@rmmslegal.com
awadhwa@rmmslegal.com

*Attorneys for Defendants/Counterclaim
Plaintiffs Lupin Atlantis Holdings SA
and Lupin Pharmaceuticals, Inc.*

OF COUNSEL:

Scott J. Bornstein
Richard C. Pettus
Michael H. Imbacuan
Jonathan D. Ball, Ph.D.
GREENBERG TRAURIG, LLP
MetLife Building
200 Park Avenue
New York, NY 10166
(212) 801-9200
bornsteins@gtlaw.com
pettusr@gtlaw.com
imbacuanm@gtlaw.com
ballj@gtlaw.com

Jonathan R. Wise
GREENBERG TRAURIG, LLP
1717 Arch Street
Philadelphia, PA 19103
(215) 988-7850
wisej@gtlaw.com

*Attorneys for Defendant/Counterclaim Plaintiff
Teva Pharmaceuticals USA, Inc.*

Dated: April 10, 2020

VIA CM-ECF

The Honorable Maryellen Noreika
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801-3555

Re: *Vifor Fresenius Medical Care Renal Pharma Ltd. et al. v. Lupin Atlantis Holdings SA et al.*, C.A. No. 18-390-MN

Dear Judge Noreika:

Defendants Lupin Atlantis Holdings SA and Lupin Pharmaceuticals, Inc. (collectively, “Lupin”), and Teva Pharmaceuticals USA, Inc. (“Teva”) (collectively, “Defendants”) submit this letter to respond to Plaintiffs’ Motion to Strike (D.I. 213) and their Opening Letter in Support (D.I. 214) (collectively, the “Motion”), in which they seek to strike the Reply Expert Report of Robert Linhardt, Ph.D., or in the alternative, to preclude Dr. Linhardt from testifying in Defendants’ case-in-chief.

As an initial matter, with respect to Plaintiffs’ request that Dr. Linhardt be precluded from testifying in Defendants’ case-in-chief, Defendants never represented that they intend to present Dr. Linhardt’s opinions in their case-in-chief. Defendants specifically told Plaintiffs that it was premature to “confirm” that Dr. Linhardt would testify “only after” Dr. Harris. As Defendants explained to Plaintiffs, the Court will decide the order of witness presentation at trial, and the order of witnesses will depend on a number of factors, including the witnesses’ availability and the Court’s convenience. Notwithstanding this, Defendants confirmed that Dr. Linhardt will present opinions within the scope of his Reply Report. Although Defendants believe it is premature, they of course have no objection to the Court setting the order of presentation of both Drs. Harris and Linhardt now, if the Court is so inclined.

With respect to Plaintiffs’ request that the Court strike Dr. Linhardt’s Reply Expert Report, the Court should deny that request outright. First and foremost, Dr. Linhardt did not provide any “new opinions” that “should have” been addressed earlier. Second, Dr. Linhardt’s Reply Report is a direct rebuttal of Dr. Harris’s new opinions and is accordingly a proper reply report. Third, not only is Plaintiffs’ Motion untimely, Plaintiffs deposed Dr. Linhardt for nearly seven hours on his single expert report. If the Court is inclined to grant Plaintiffs’ Motion, Defendants request that the Court grant Defendants alternative relief, namely, exclusion of the corresponding opinions of Dr. Harris.

I. Claim Construction, Written Discovery and Expert Discovery

During the claim construction proceedings, Dr. Harris provided a declaration in support of his construction of the term “not bound as a complex compound” as recited in claim 31 of the ‘251 patent. (D.I. 66). Notably, although the terms “essentially non-bioabsorbable” in claim 29 and “iron release rate of below 2.5%” in claim 30 were also part of claim construction, Dr. Harris’s claim construction declaration did not address those terms. Instead, Plaintiffs submitted a declaration from their formulation expert, Dr. Williams, in support of their construction of the

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claim term “iron release rate of below 2.5%.” During fact discovery, Plaintiffs provided supplemental responses to interrogatories relating to claims 29, 30 and 31. (Ex. A, Plaintiffs’ Supp. Resps. to Interrogatory No. 2 (“Supp. Resps.”) at 11-13, 22, 31-33, 47-50).

During expert discovery, Defendants’ expert, Dr. Chambliss, relied upon Dr. Harris’s claim construction declaration admissions for his opinions concerning the “not bound as a complex compound” limitation in claim 31. For the first time, in his Rebuttal Report, Dr. Harris offered opinions that were directly contrary to his claim construction declaration. (Ex. B, Harris Rebuttal at 41-45). Moreover, Dr. Harris provided opinions on claims 29, 30 and 31 that were not included or suggested in any of Plaintiffs’ written discovery. Dr. Harris’s new opinions and Dr. Linhardt’s corresponding rebuttal in the Linhardt Reply Report are as follows:

- The difference in temperature between spray drying and concentrating on a rotovap could make a significant difference in the chemical properties of the final premix (*compare* Ex. B, Harris Rebuttal ¶¶ 47, 103, *with* Ex. C, Linhardt Reply¹ ¶¶ 52-59);
- The pH at which the stabilization agent is added affects complex formation (*compare* Ex. B ¶¶ 62, 84, 97, 103, 115, 119, 128, *with* Ex. C ¶¶ 60-65, 117-119);
- The amount of stabilizing agent added per unit iron will also impact solubility (*compare* Ex. B ¶¶ 65, 98, 129, *with* Ex. C ¶¶ 66-69);
- The type of stabilization agent and excipients included in the final formulation affect complex formation (*compare* Ex. B ¶¶ 66-68, 90, 96, 126, *with* Ex. C ¶¶ 70-79, 97-98);
- The process used to formulate the stabilized iron oxyhydroxides may also impact the solubility of the resulting formulation (*compare* Ex. B ¶¶ 69, 99, 103, 130, *with* Ex. C ¶¶ 80-82);
- The use of mannitol as a stabilization agent (*compare* Ex. B ¶¶ 85, 116, *with* Ex. C ¶¶ 92, 120);
- In Hergesell 1, that a POSA would know that the radiolabeled iron was prepared through a different method (*compare* Ex. B ¶¶ 91-93, 121-23, *with* Ex. C ¶¶ 99-103, 126-30); and
- [REDACTED]

II. Dr. Linhardt Provides Direct Rebuttal of Dr. Harris’s New Opinions

Plaintiffs cannot be prejudiced by Dr. Linhardt’s opinions, which directly respond to new opinions of Dr. Harris and contentions of Plaintiffs that were never previously raised during this litigation. Dr. Linhardt thoroughly disproved each of Dr. Harris’s new rebuttal opinions in his Reply Report and at his seven-hour deposition. Recognizing that Dr. Linhardt’s testimony undercuts Dr. Harris’s new opinions, Plaintiffs now seek to exclude Dr. Linhardt from testifying at trial, but they do not contend that Dr. Linhardt’s opinions are unreliable or dispute his qualifications. Nor can they. Thus, the Court should deny Plaintiffs’ Motion.

Instead, Plaintiffs allege that Defendants served a reply report from a “new expert” who offered “new opinions” on inherency. (D.I. 214 at 1). Defendants disagree. Defendants’ so-

¹ The full Linhardt Reply Report is attached as Exhibit 1 to Plaintiffs’ Opening Letter (D.I. 214).

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called “new” expert’s “new” opinions were in direct response to Dr. Harris’s new inherency opinions revealed for the first time in his Rebuttal Report (as outlined above). Plaintiffs base their argument on the Scheduling Order, but crucially leave out that Plaintiffs served amended and supplemental responses to Defendants’ Interrogatory No. 2, related to validity, that do not include any of these new inherency opinions or corresponding documents relied on in connection therewith. (Ex. A, Supp. Resps. at 11-13, 22, 31-33, 47-50). Based on Plaintiffs’ written discovery disclosures and Dr. Harris’s previous claim construction declaration, Dr. Chambliss served an opening report showing that the clear language of the disclosures in the prior art fully anticipates the asserted claims 29, 30 and 31. (Ex. D, Chambliss Opening ¶¶ 203-12, 309-21). Dr. Chambliss provided his opinions from the perspective of a skilled person, opining that certain inherent properties of iron oxy-hydroxide were apparent based on his review of the relevant references and were confirmed by Plaintiffs’ own internal documents and Rule 30(b)(6) testimony. In response to Dr. Chambliss’s opinions, Plaintiffs submitted Dr. Harris’s Rebuttal Report, which included, *inter alia*, the new opinions enumerated above. These new opinions were focused on the chemical nature of the stabilized iron oxy-hydroxide and its interactions with other excipients in a formulation. (Cf. Ex. A, Supp. Resps. at 11-13, 22, 31-33, 47-50).

None of these new positions could have been reasonably anticipated or addressed in an opening report, and were properly and timely addressed in Dr. Linhardt’s Reply. *See, e.g., Withrow v. Spears*, 967 F. Supp. 2d 982, 1001 (D. Del. 2013) (“A rebuttal or reply expert report is proper if the intent of the report is ‘solely to contradict or rebut evidence on the same subject matter identified’ by the opposing party’s expert report.”) (citation omitted); *see also Helios Software, LLC v. SpectorSoft Corp.*, 2014 WL 4796111, at *3 (D. Del. Sept. 18, 2014) (“[C]ourts need not automatically exclude anything an expert could have included in his or her original report. Such a rule would lead to the inclusion of vast amounts of arguably irrelevant material in an expert’s report on the off chance that failing to include any information in anticipation of a particular criticism would forever bar the expert from later introducing the relevant material. All that is required is for the information to repel other expert testimony.”); *Astellas Pharma Inc. v. Actavis Elizabeth LLC*, 2019 WL 2265570, at *2 (D. Del. May 13, 2019) (permitting Astellas’s expert to file reply report in response to new evidence and data not disclosed in Actavis’s interrogatory responses but raised in Actavis’s rebuttal expert report).

Plaintiffs’ allegation that Dr. Linhardt was an “entirely new expert” is irrelevant. *See Masimo Corp. v. Philips Elec. N. Am. Corp.*, 2016 WL 4394359, at * 2 (D. Del. Aug. 15, 2016) (“[T]here’s nothing, per se, improper in using a different expert in a reply report than was used in the opening reports.”) (internal quotation marks omitted); *Fed. Trade Comm’n v. Innovative Designs, Inc.*, 2018 WL 3611510, at *3 (W.D. Pa. July 27, 2018) (noting that a rebuttal report from an additional expert, while overlapping with the opening report, was proper). The proper legal standard is whether “the intent of the report is solely to contradict or rebut evidence on the same subject matter identified by the opposing party’s expert report.” *See Withrow*, 967 F. Supp. 2d at 1001. This is precisely the case for the Linhardt Reply Report—Dr. Linhardt’s opinions were offered in reply solely to the new opinions of Dr. Harris.

Plaintiffs further allege that Dr. Linhardt’s opinions were “designed to replace Dr. Chambliss’s flawed opinions, not to respond to Dr. Harris.” (D.I. 214 at 1). Not so. Rather, Dr. Linhardt corrected Dr. Harris’s misreading of Dr. Chambliss’s Opening Report based on the

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chemical nature of the prior art. The opinions of Dr. Linhardt, addressing Dr. Harris's new opinions, confirmed Dr. Chambliss's opinions from his Opening Report that were focused on the explicit recitations in the prior art showing that the claims at issue were inherently anticipated. Dr. Linhardt replied to Dr. Harris's new positions and disproved each and every one, including demonstrating that the opinions in Dr. Harris's Rebuttal Report actually support Dr. Chambliss's opinions that the inventions of claims 29, 30, and 31 of the '251 patent are inherently disclosed and anticipated in the prior art. (*See, e.g.*, Ex. C ¶¶ 85, 105-108, 132-134, 139, 145, 146, 149).

Plaintiffs essentially demand that Defendants should have presented Dr. Linhardt as an anticipatory rebuttal to Dr. Harris's previously undisclosed opinions. Even if Dr. Linhardt could have done so (neither he nor Dr. Chambliss could have guessed Dr. Harris's new opinions), it is not a basis for exclusion. *Helios*, 2014 WL 4796111, at *3 (“[C]ourts need not automatically exclude anything an expert could have included in his or her original report. Such a rule would lead to the inclusion of vast amounts of arguably irrelevant material in an expert's report on the off chance that failing to include any information in anticipation of a particular criticism would forever bar the expert from later introducing the relevant material. All that is required is for the information to repel other expert testimony.”); *see also Masimo*, 2016 WL 4394359, at * 2 (“[O]pening reports . . . don't have to address every possibility under the sun that could come up in response to your opening [reports] for fear that [if] you do not anticipate everything you'll never be heard on it.”). Plaintiffs do not dispute that Dr. Linhardt's report counters Dr. Harris's opinions; rather, having been unable to attack Dr. Linhardt's opinions during his deposition, Plaintiffs now seek to have those opinions excluded.

Plaintiffs' final allegation is that Dr. Linhardt's opinions could have been presented in an opening report because he relies on “Dr. Chambliss, the prior art, and Vifor's inventor testimony and internal documents.” (D.I. 214 at 2). The fact that Dr. Linhardt may rely, in part, on the prior art and Plaintiffs' own documents admitting inherency does not change the fact that Dr. Linhardt was replying to the new opinions of Dr. Harris.

II. Plaintiffs Raised These Issues During Expert Discovery, but Refused Any Discussion Other Than Wholesale Exclusion

During the parties' January 2020 meet and confer, Defendants requested that Plaintiffs articulate a proper basis for excluding the Linhardt Reply Report in view of the new opinions raised by Dr. Harris. (Ex. E, R. Pettus email of 1/13/2020). Once Defendants requested this information, this issue was never raised again by Plaintiffs until the current Motion. Defendants might have been amenable to a sur-reply report from Plaintiffs, but instead, Plaintiffs chose to table the issue (despite the Court's instruction during the February 6, 2020 dispute hearing that the parties should present *all* pending discovery disputes). Plaintiffs then deposed Dr. Linhardt for almost the entire seven hours allowed, but still never raised any alleged impropriety of his opinions. Not satisfied with the result of Dr. Linhardt's deposition, Plaintiffs brought the current Motion. Plaintiffs inexplicably did not raise this issue with the Court immediately after the parties' January meet and confer, during Dr. Linhardt's deposition or at the February 6 dispute hearing, and the Court should not permit Plaintiffs to raise this issue at this time. Nor is Plaintiffs' Motion a proper *Daubert* motion as required by the Scheduling Order. (D.I. 28 at 6-7).

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III. The *Pennypack* Factors Favor the Inclusion of Dr. Linhardt's Testimony

Notwithstanding that the Linhardt Reply Report was timely served, Plaintiffs make no credible showing of actual prejudice, much less the prejudice necessary for exclusion under the *Pennypack* factors. See *Novartis Pharm. Corp. v. Actavis, Inc.*, 2013 WL 7045056, at *7 (D. Del. Dec. 23, 2013). Plaintiffs agree that Fed. R. Civ. P. 37(c) does not preclude a party from relying on late-disclosed evidence if "the failure was substantially justified or is harmless." (See D.I. 214 at 2). This Court has recognized that because "[t]he exclusion of critical evidence is an extreme sanction," this remedy should not be imposed where an untimely or improper expert disclosure amounts to only a 'slight deviation from pre-trial notice requirements' or occasions only 'slight prejudice' to the movant." *Novartis*, 2013 WL 7045056, at *6 (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994)). The applicable factors do not justify exclusion here and Plaintiffs cannot demonstrate otherwise:

- (1) Plaintiffs cannot credibly claim surprise because it was impossible for Dr. Linhardt (or any other expert, including Dr. Chambliss) to provide any so-called "new opinions" in an opening report because Defendants did not know of Dr. Harris's new opinions until the filing of his rebuttal report. Nor can Plaintiffs credibly claim prejudice, as Dr. Linhardt was deposed for nearly seven hours;
- (2) Plaintiffs had the ability to cure any prejudice, not only by taking Dr. Linhardt's deposition, but, to the extent that there was a specific cure Plaintiffs sought (other than wholesale exclusion), Plaintiffs could have raised that issue, but instead went radio-silent following the parties' initial meet and confer and did not respond to Defendants' requests. (Ex. E, R. Pettus email of 1/13/2020);
- (3) Plaintiffs do not allege there is a disruption to the trial;
- (4) There was no bad faith on the part of Defendants because, as noted herein, Dr. Linhardt's opinions are a direct reply to new opinions of Dr. Harris; and
- (5) The evidence offered by Dr. Linhardt is important to the trial. Among other things, Dr. Linhardt responds to new opinions that were not disclosed during fact discovery. See *Withrow*, 967 F. Supp. 2d at 1000 ("[T]he exclusion of critical evidence is an extreme sanction," and "evidence should be excluded sparingly and only in circumstances involving litigation conduct that is clearly unprofessional or inappropriate, and in circumstances creating prejudice.".)²

For at least these reasons, Defendants requests that the Court deny Plaintiffs' Motion. Counsel are available at the convenience of the Court should Your Honor have further questions. A Proposed Order is submitted herewith.

² If anything is to be stricken, it should be the new opinions of Dr. Harris, which were served in violation of the governing schedule for written discovery and final contentions and prejudice Defendants. See *Intellectual Ventures I LLC v. AT&T Mobility LLC*, 2017 WL 658469, at *6 (D. Del. Feb. 14, 2017) (striking portions of plaintiffs' expert report where plaintiffs injected new theories two months after final contentions).

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Respectfully submitted,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)
David A. Bilson (#4986)
PHILLIPS, MCLAUGHLIN & HALL, P.A.
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
dab@pgmhlaw.com

OF COUNSEL:

William A. Rakoczy
Anuj K. Wadhwa
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, Illinois 606054
(312) 222-6301
wrakoczy@rmmslegal.com
awadhwa@rmmslegal.com

*Attorneys for Defendants/Counterclaim
Plaintiffs Lupin Atlantis Holdings SA
and Lupin Pharmaceuticals, Inc.*

Respectfully submitted,

/s/ Nathan R. Hoeschen

John W. Shaw (No. 3362)
Karen E. Keller (No. 4489)
Nathan R. Hoeschen (No. 6232)
SHAW KELLER LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
(302) 298-0700
jshaw@shawkeller.com
kkeller@shawkeller.com
nhoeschen@shawkeller.com

OF COUNSEL:

Scott J. Bornstein
Richard C. Pettus
Michael H. Imbacuan
Jonathan D. Ball, Ph.D.
GREENBERG TRAURIG, LLP
MetLife Building
200 Park Avenue
New York, NY 10166
(212) 801-9200
bornsteins@gtlaw.com
pettusr@gtlaw.com
imbacuanm@gtlaw.com
ballj@gtlaw.com

Jonathan R. Wise
GREENBERG TRAURIG, LLP
1717 Arch Street
Philadelphia, PA 19103
(215) 988-7850
wisej@gtlaw.com

*Attorneys for Defendant/Counterclaim Plaintiff
Teva Pharmaceuticals USA, Inc.*